SOP Template: Root Cause Analysis

This SOP defines the process for conducting **Root Cause Analysis** to systematically identify the underlying causes of problems or incidents. It includes steps for data collection, problem definition, cause identification, analysis techniques such as the 5 Whys and Fishbone Diagram, corrective action planning, implementation, and verification. The goal is to prevent recurrence by addressing the fundamental issues rather than symptoms, improving overall organizational processes and safety.

1. Purpose

To ensure a structured, consistent, and effective approach to identifying and eliminating root causes of problems or incidents, thereby boosting organizational performance and safety.

2. Scope

This SOP applies to all employees involved in problem-solving, quality assurance, process improvement, incident investigation, and corrective action activities.

3. Responsibilities

- **Process Owner:** Ensures RCA is conducted as per this SOP.
- **Investigation Team:** Gathers data, performs analysis, recommends actions.
- **Managers/Supervisors:** Implements and tracks corrective actions.

4. Root Cause Analysis Procedure

1. **Initiate RCA**
   - Define the problem/incident.
   - Appoint an RCA facilitator/team.
2. **Data Collection**
   - Gather relevant data, logs, records, and witness statements.
   - Document timeline of events.
3. **Problem Definition**
   - Clearly state the problem, impact, and scope.
4. **Cause Identification & Analysis**
   - Use analysis techniques such as:
     - **5 Whys:** Repeatedly ask "Why?" to drill down to the root cause.
     - **Fishbone (Ishikawa) Diagram:** Categorize possible causes (People, Methods, Machines, Materials, Measurements, Environment).
     - Other tools (Pareto Chart, Fault Tree Analysis) if needed.
5. **Identify Root Cause**
   - Agree on the true underlying cause(s) supported by evidence.
6. **Corrective Action Planning**
   - Develop action plan(s) to eliminate root causes and prevent recurrence.
   - Assign responsibilities and deadlines.
7. **Implement Corrective Actions**
   - Execute the corrective actions as per plan.
8. **Verification & Effectiveness Check**
   - Monitor outcomes to confirm resolution and prevent recurrence.
   - Document results and close the case.
9. **Documentation & Reporting**
   - Complete RCA documentation, attach evidence, and submit a final report for management review.

5. Documentation Template

Section	Details
Problem / Incident Description	
Team Members	
Timeline of Events	

Data Collected	
Analysis Technique Used (5 Whys, Fishbone, etc.)	
Root Cause(s) Identified	
Corrective Actions	
Action Owner(s)	
Deadline(s)	
Verification Method	
Status / Closure Date	

6. References

- ISO 9001: Quality Management Systems
- Company-specific incident management policy
- Lean Six Sigma Tools and Methods

7. Revision History

Version	Date	Description	Author
1.0	2024-06-14	Initial SOP Release	[Your Name]